**Citation:**

DeJongh ED, Binkley TL, Specker BL. Fat mass gain is lower in calcium-supplemented than in unsupplemented preschool children with low dietary calcium intakes. AM J Clin Nutr. 2006;84:1123-1127.

**PubMed ID:** 17093165

**Study Design:**

randomized controlled trial

**Class:**

A - Click here for explanation of classification scheme.

**Research Design and Implementation Rating:**

POSITIVE: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

The study's purpose was to determine whether an association existed between change in percentage body fat or fat mass and calcium intake in children aged 3-5 y.

**Inclusion Criteria:**

Subjects were children in one of eleven participating childcare centers who were enrolled in a one year randomized calcium and activity trial.

**Exclusion Criteria:**

Children who had any disorder known to influence bone metabolism were excluded from this study.

**Description of Study Protocol:**

**Recruitment** Subjects were children 3-5 years old who were already recruited from 11 childcare centers participating in a trial of physical activity and calcium supplementation. No other specific data about subjects was given in this report.

**Design** Secondary analysis of data from a one year randomized calcium and activity trial

**Blinding used (if applicable)** This report states that the one year randomized calcium and activity trial was partially blinded, however no details of blinding were given in this report.

**Intervention (if applicable)**

- After stratification of childcare centers and participant's sex, each child was assigned to a

fine or a gross motor activity schedule of 30 min/d, 5 d/wk, for 12 mo.
- Children received either a daily calcium carbonate supplement of 1000mg calcium or a placebo .

**Statistical Analysis**

- Descriptive statistics were compared between supplement groups
- General linear models were used to determine the significance of total calcium intake on changes in the percentage of total body fat and body composition after control for covariates.
- Sex-by-supplement and activity-by-supplement interactions were tested.
- Individuals with low calcium or low energy intakes were categorized into tertiles and subset analysis were performed within the lowest tertile of either calcium or energy intake.

**Data Collection Summary:**

**Timing of Measurements**

- Measures of dietary intake and physical activity were obtained at baseline and at 6 and 12 months
- Body fat was measured by dual-energy X-ray absorptiometry at baseline and at 12 months.

**Dependent Variables**

- body composition changes measured by dual-energy X-ray absorptiometry

**Independent Variables**

- Children randomly assigned to participate in either a fine motor or gross motor activity group for 30 min/d, 5d/wk, for 12 mo. The fine motor group performed activities designed to keep them sitting quietly. Children in the gross motor group performed activities designed to provide 5 min. of warm-up, which were followed by 20 min. of jumping, hopping, and skipping activities and concluded with 5 min of cool-down. At baseline, 6 and 12 months, activity was measured using 48-hr accelerometer readings.
- Mean dietary and total (dietary plus supplements) calcium intakes were calculated at baseline, 6 and 12 months using 3 day diet diaries.

**Control Variables** Age and maternal BMI

**Description of Actual Data Sample:**

**Initial N**: 178

**Attrition (final N):** 176

**Age**: 3-5 year old children

**Ethnicity**: Not stated

**Other relevant demographics**: 93 boys, 83 girls

**Anthropometrics:** See population characteristics by supplement group table below.

**Location**: Not specifically stated (researchers from Brookings, South Dakota).

**Summary of Results:**

**Key Findings**

**Subject characteristics and univariate analyses:**

- Change in fat mass was not associated with the percentage of time engaged in moderate plus vigorous activity (r = -0.10, P= 0.18) and they did not differ by activity group (0.5±0.8 kg in fine and gross motor groups, respectively; P= 0.99).
- Change in fat mass did not differ between children in the calcium and placebo groups (0.5±0.9 and 0.6±0.8 kg respectively; P= 0.32). Similar findings were observed for changes in percentage body fat.
- No significant correlations between changes in body composition and dietary calcium and total calcium intake were observed (percent body fat, fat mass, and lean mass).

**Sex-specific effects of calcium supplementation:**

- The sex by supplementation group interaction was not significant for either changes in total-body fat mass (P= 0.32) or changes in total-body lean mass (p= 0.32)
- Sex by supplementation group interaction was nearly significant for changes in total percentage body fat in a model that controlled for age and maternal BMI (P= 0.08). The boys tended to have a greater decrease in percentage body fat than did the girls(-2.0± 0.4% and -0.5± 0.4%; least square means ± SE); however, this was not observed in the placebo group.
- The activity by supplementation group interaction was not significant for either change in total percentage body fat (P=0.12) or change in fat or lean mass (P=0.29 and P=0.66).

**Influence of calcium on body-composition changes in children with a low dietary calcium intake or a low energy intake**

- There were no differences in changes in percentage body fat or lean mass by calcium supplementation group in the children in the lowest tertile of dietary calcium intake (<821 mg/d; n= 25 boys and 32 girls)
- In the children of the lowest tertile of dietary calcium intake, a change of fat mass was lower in the calcium supplemented group than in the placebo group (0.3±0.5 and 0.8±1.1 kg;P=0.04), but the group-by-tertile interaction (lowest vs highest 2 tertiles) showed only borderline significance (P=0.08)
- No significant correlations were observed between the changes in body composition and total calcium intake within the lowest tertile of dietary calcium intake. The inclusion of age or age and maternal BMI in the regression models did not alter these findings.
- The sex-by-supplementation group and sex-by-total calcium intake interactions were not significant for any of the changes in body composition (percentage body fat, fat mass, and lean mass; P>0.3 for all interactions)
- In children in the lowest tertile of energy intake (<1435 kcal/d), no significant differences in the changes in body compostion by calcium supplementation group and no significant correlations between changes in body composition and total calcium intake were observed.

Population characteristics by supplement group[1]

| | Boys | | Girls | |
|---|---|---|---|---|
| | Placebo group (n=46) | Calcium group (n=47) | Placebo group (n=42) | Calcium group (n=41) |
| Anthropometric characteristics | | | | |
| Total body fat (%) | | | | |
| Baseline | 23.1±3.5 | 24.0±3.6 | 27.8±4.6 | 27.8±4. |
| Change | -1.1±2.2[2] | -2.0±2.5[2] | -.08±2.4[2] | -.05±3.1[2] |
| Total body fat mass (kg) | | | | |
| Baseline | 4.0±1.0 | 4.2±0.9 | 4.7±1.2 | 4.8±1.3 |
| Change | 0.4±0.8[2] | 0.20.7[2] | 0.7±0.8[2] | 0.7±1.0[2] |
| Total body lean mass (kg) | | | | |
| Baseline | 12.8±1.5 | 12.6±1.4 | 11.5±1.6 | 11.6±1.8 |
| Change | 2.0±0.6[2] | 2.0±0.7[2] | 2.0±0.6[2] | 1.8±0.6[2] |
| Dietary characteristics | | | | |
| Baseline calcium intake (mg/d) | 968±252 | 961±309 | 866±196 | 925±346 |
| Calcium intake(mg/d)[3] | | | | |
| Diet | 1028±277 | 969±247 | 860±197 | 936±282 |
| Supplements | 0 | 425±164[4] | 0 | 375±192[4] |
| Total | 1028±277 | 1395±237[4] | 860±197 | 1310±356[4] |
| Energy intake(kcal)[3] | 1608±300 | 1621±235 | 1475±234 | 1512±257 |
| Total fat intake (g)[3] | 57±16 | 57±11 | 52±10 | 56±11 |
| Protein intake (g)[3] | 58±8 | 58±12 | 52±11 | 53±12 |

[1]The sex-by-supplementation group interaction term was nearly significant for changes in total-body percentage fat (P=0.08) after control for age and maternal BMI. This interaction term was not significant for changes in total-body fat mass (P=0.32) or in total-body lean mass (p=0.32). [2] Change significantly different from 0, P<0.05. [3]Mean intake based on baseline, 6 mo, and 12 mo 3-d diet records. [4]Significantly different from placebo within sex group, P<0.01.

Correlation coefficients (r) for changes in body composition (12 mo-baseline) by mean total (diet + supplement) calcium intake for the lowest and highest 2 tertiles of mean dietary calcium intake and energy intake [1]

| Total calcium intake versus | Change in body fat (%) | Change in fat mass (kg) | Change in lean mass (kg) |
|---|---|---|---|
| Mean dietary calcium intake[2] | | | |
| Lowest tertile, <821 mg/d | -0.18 | -02 | 0.05 |

| | | | |
|---|---|---|---|
| *P*[3] | 0.18 | 0..13 | 0.70 |
| Highest 2 tertiles, ≥821 mg/d | 0.04 | -0.00 | -0.13 |
| *P*[3] | 0.71 | 0.98 | 0.18 |
| Mean dietary energy intake[2] | | | |
| Lowest tertile, <1435 kcal/d | 0.02 | 0.02 | 0.15 |
| *P*[3] | 0.91 | 0.88 | 0.27 |
| Highest 2 tertiles, ≥1435 kcal/d | -0.02 | -0.07 | 0.02 |
| *P*[3] | 0.81 | 0.48 | 0.85 |

[1]The mean total calcium intake-by-tertile of mean dietary calcium intake (lowest vs highest 2 tertiles) interaction was not significant for any of the changes in body composition. [2]Mean intake was based on baseline, 6 mo, and 12 mo 3 d diet records. [3]Represents th significance of the main effect of calcium supplementation group.

**Other Findings**

**Author Conclusion:**

In this study, the authors found no consistent relation between changes in total percentage body fat in young children and either dietary calcium intake or total calcium intake, even when the analyses were limited to the children in the lowest tertile of calcium intake or the lowest tertile of energy intake. Among the children in the lowest tertile of dietary calcium intake, a smaller gain in fat mass was observed among children randomly assigned to receive calcium supplements than in children randomly assigned to receive placebo. However, the correlation between change in fat mass and total calcium intake, from both diet and supplements, was not significant in this group of children and did not support the hypothesis that changes in fat mass were associated with increased calcium intake.

***Reviewer Comments:***

***Research Design and Implementation Criteria Checklist: Primary Research***

**Relevance Questions**

| | | |
|---|---|---|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | Yes |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | Yes |

| | | |
|---|---|---|
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | Yes |

**Validity Questions**

| | | |
|---|---|---|
| **1.** | **Was the research question clearly stated?** | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |
| 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated? | Yes |
| 1.3. | Were the target population and setting specified? | Yes |
| **2.** | **Was the selection of study subjects/patients free from bias?** | Yes |
| 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| 2.2. | Were criteria applied equally to all study groups? | Yes |
| 2.3. | Were health, demographics, and other characteristics of subjects described? | Yes |
| 2.4. | Were the subjects/patients a representative sample of the relevant population? | No |
| **3.** | **Were study groups comparable?** | Yes |
| 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT) | Yes |
| 3.2. | Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline? | Yes |
| 3.3. | Were concurrent controls used? (Concurrent preferred over historical controls.) | Yes |
| 3.4. | If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? | N/A |
| 3.5. | If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.) | N/A |

| | | |
|---|---|---|
| 3.6. | If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")? | N/A |
| **4.** | **Was method of handling withdrawals described?** | Yes |
| 4.1. | Were follow-up methods described and the same for all groups? | Yes |
| 4.2. | Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.) | Yes |
| 4.3. | Were all enrolled subjects/patients (in the original sample) accounted for? | Yes |
| 4.4. | Were reasons for withdrawals similar across groups? | Yes |
| 4.5. | If diagnostic test, was decision to perform reference test not dependent on results of test under study? | N/A |
| **5.** | **Was blinding used to prevent introduction of bias?** | ??? |
| 5.1. | In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate? | ??? |
| 5.2. | Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.) | ??? |
| 5.3. | In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded? | N/A |
| 5.4. | In case control study, was case definition explicit and case ascertainment not influenced by exposure status? | N/A |
| 5.5. | In diagnostic study, were test results blinded to patient history and other test results? | N/A |
| **6.** | **Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?** | Yes |
| 6.1. | In RCT or other intervention trial, were protocols described for all regimens studied? | Yes |
| 6.2. | In observational study, were interventions, study settings, and clinicians/provider described? | N/A |
| 6.3. | Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect? | Yes |
| 6.4. | Was the amount of exposure and, if relevant, subject/patient compliance measured? | Yes |
| 6.5. | Were co-interventions (e.g., ancillary treatments, other therapies) described? | N/A |
| 6.6. | Were extra or unplanned treatments described? | N/A |

| | | |
|---|---|---|
| 6.7. | Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups? | Yes |
| 6.8. | In diagnostic study, were details of test administration and replication sufficient? | N/A |
| **7.** | **Were outcomes clearly defined and the measurements valid and reliable?** | Yes |
| 7.1. | Were primary and secondary endpoints described and relevant to the question? | Yes |
| 7.2. | Were nutrition measures appropriate to question and outcomes of concern? | Yes |
| 7.3. | Was the period of follow-up long enough for important outcome(s) to occur? | Yes |
| 7.4. | Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures? | Yes |
| 7.5. | Was the measurement of effect at an appropriate level of precision? | Yes |
| 7.6. | Were other factors accounted for (measured) that could affect outcomes? | Yes |
| 7.7. | Were the measurements conducted consistently across groups? | Yes |
| **8.** | **Was the statistical analysis appropriate for the study design and type of outcome indicators?** | Yes |
| 8.1. | Were statistical analyses adequately described and the results reported appropriately? | Yes |
| 8.2. | Were correct statistical tests used and assumptions of test not violated? | Yes |
| 8.3. | Were statistics reported with levels of significance and/or confidence intervals? | Yes |
| 8.4. | Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)? | N/A |
| 8.5. | Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)? | Yes |
| 8.6. | Was clinical significance as well as statistical significance reported? | N/A |
| 8.7. | If negative findings, was a power calculation reported to address type 2 error? | N/A |
| **9.** | **Are conclusions supported by results with biases and limitations taken into consideration?** | Yes |
| 9.1. | Is there a discussion of findings? | Yes |
| 9.2. | Are biases and study limitations identified and discussed? | Yes |
| **10.** | **Is bias due to study's funding or sponsorship unlikely?** | Yes |

| | | |
|---|---|---|
| 10.1. | Were sources of funding and investigators' affiliations described? | Yes |
| 10.2. | Was the study free from apparent conflict of interest? | Yes |